

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
ETERNAL HEALTH, INC., d/b/a YEARS	§	DALLAS COUNTY, T E X A S
TO YOUR LIFE HEALTH CENTERS	§	
and CYNTHIA PITRE, individually,	§	
Defendants.	§	____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General GREG ABBOTT, filing Plaintiff's Original Petition complaining of and against Defendants ETERNAL HEALTH, INC., d/b/a YEARS TO YOUR LIFE HEALTH CENTERS and CYNTHIA PITRE, individually, ("herein after Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE" or "Defendants"), based on their advertising and operating a health-related clinic using prescription medical devices without physician involvement, unapproved medical devices, and unapproved new drugs or misbranded food and would respectfully show the court the following:

JURISDICTION

1. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the STATE OF TEXAS and in the public interest under the authority granted to him by §431.047 (b) of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. ("TFDCA") and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of Health of the State of Texas and his authorized

agents find that Defendants have violated and have threatened to violate provisions of §431.021 of the TFDCA.

2. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the State of Texas under the authority granted to him by §17.47 of the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*, (“DTPA”) upon the grounds that Defendants have engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by §17.46 (a) and (b) of the DTPA.

PARTY DEFENDANTS

3. Defendant CYNTHIA PITRE is an individual who owns and directs Defendant ETERNAL HEALTH, INC., d/b/a YEARS TO YOUR LIFE at three locations in Dallas County, 237 W. Page, Dallas, Texas 75208; 1221 W. Airpost Fwy., Suite 217, Irving, Texas 75062; and 1712 W. Frankford, #104, Carrollton, Texas 75007. Defendant ETERNAL HEALTH, INC., d/b/a YEARS TO YOUR LIFE may be served with process through serving DEFENDANT CYNTHIA PITRE, President and owner, at her home address of 2842 Bonnywood Lane, Dallas, Texas 75201.

Defendant CYNTHIA PITRE, individually may be served with process by serving her at her home address 2842 Bonnywood Lane, Dallas, Texas 75201.

VENUE

4. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA by virtue of the fact that Defendants engaged in the business of advertising and operating a health-related clinic using prescription colon irrigation systems, unapproved medical devices, and unapproved new drugs or misbranded food in Dallas County, Texas.

5. Venue of this action lies in Dallas County on the basis of §431.047 (c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants engaged in the business of advertising and operating a health-related clinic using prescription colon irrigation systems, unapproved medical devices, and unapproved new drugs or misbranded food in Dallas County, Texas.

PUBLIC INTEREST

6. By reason of the institution and operation of the unlawful practices set forth herein, Defendants have and will cause immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and will also cause adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

TRADE AND COMMERCE

7. Defendants are engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that they were engaged in the business of advertising and/or marketing and delivering colon cleansing services in Texas.

NOTICE BEFORE SUIT

8. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with the Defendants herein to inform Defendants of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested.

ACTS OF AGENTS

9. Whenever in this petition it is alleged that Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was

performed by the officers, agents or employees of said Defendants, and in each instance, the officers, agents or employees of said Defendants that were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of the Defendants.

OVERVIEW OF NATURE OF DEFENDANT'S OPERATION

10. Defendants advertise, market, and provide colon cleansing services to treat cancer, arthritis, restore the immune system, and for general well-being; ozone steam spa treatments to oxygenate, detoxify and cleanse the lymphatic system; foot bath to remove cholesterol deposits, heavy metals, and uric acid from the body and detoxify the liver, kidney, bladder, etc.; and dietary supplements that claim to treat appendicitis, arthritis, bubonic plague, cancer, diabetes and other diseases. Defendants advertised and delivered the above services three offices located in Irving, Carrollton, and Dallas, Texas area, as shown below.

11. Defendants advertise and promote the use of colon irrigation systems that FDA has only cleared for a Class II intended use, as defined in 21 CFR 876.5210, for colon cleansing when medically indicated, such as before radiological or endoscopic examinations. Based upon this intended use, FDA has limited the use of all colon irrigation systems cleared for marketing to prescription use only. Therefore, all colon irrigation systems cleared for marketing by FDA are required to bear the statement on their labels that "Federal Law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word 'physician, dentist, veterinarian, or with the description designation of any other practitioner licensed by the law of the State in which he practices to use and order the use of the device¹.

¹Under Texas law, the only practitioner licensed to use prescription colon irrigation systems on humans are those licensed by the Texas Board of Medical Examiners. Therefore, in this petition, when the term "practitioner" is used, it refers only to those persons licensed by the Texas Board of Medical Examiners.

12. In a Warning Letter to Colon Therapeutics, Inc., the manufacturer of Defendants' prescription colon irrigation systems, FDA informed Defendants that "(w)hen FDA cleared the 510(k)s for the Jimmy John rectal nozzles, an accessory of the Jimmy John colonic irrigation system, we indicated that our clearance was limited to prescription use only." FDA continues that both the colon irrigation system and the rectal nozzles were cleared for the same intended use as defined in 21 CFR 876.5220 and concludes that the Jimmy John III colon irrigation system is misbranded because its labeling fails to bear the prescription legend.

13. Defendant CYNTHIA PITRE is not a licensed practitioner as defined by 25 T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act.

14. Defendants purchased and received in commerce seven prescription colon irrigation systems and thousands of prescription rectal nozzles from Colon Therapeutics, Inc., and Jimmy Girouard without authorization from a licensed practitioner to purchase or possess them as required by state and federal law, and, therefore, misbranded them.

15. Defendants used these prescription colon irrigation systems to provide colon cleansing to thousands of patients in the Irving, Carrollton, and Dallas areas without a licensed practitioner ordering a procedure on a patient and without a licensed practitioner supervising her use of the prescription medical devices. This use without practitioner involvement, as required by state and federal law, misbranded Defendants' devices.

16. Defendants used these prescription medical devices for other purposes than the approved intended use of colon cleansing when medically indicated as shown below. Defendants' use of these prescription colon irrigation systems for colon cleansing for the treatment of diseases, such as cancer, arthritis, to restore the immune system, and for general well being, uses that have not been approved by the FDA as safe and effective, adulterated these devices.

17. Defendants continued to perform colon cleansing without practitioner involvement even after they had been informed by the Texas Department of Health (“TDH”), on November 13, 14, 15, 2002 and December 12, 2002, that the colon irrigation systems that were in their possession were prescription medical devices and could only be purchased and/or possessed, used upon the order of, and the use supervised by a licensed practitioner.

18. Defendants also advertise and provide treatment for patients using Ozone Spas devices to oxygenate, detoxify and cleanse the lymphatic system when these devices have not received marketing clearance from the Federal Food and Drug Administration (“FDA”) for any purpose; Bio-Cleanse devices (foot bath) to remove cholesterol deposits, heavy metals, and uric acid from the body and detoxify the liver, kidney, bladder when these devices have not received marketing clearance from the FDA for any purpose; and dietary supplements that claim to treat appendicitis, arthritis, bubonic plague, cancer, diabetes and other diseases which make these products misbranded foods and/or unapproved new drugs that have not received marketing clearance from the FDA as drugs.

19. Defendants advertised on the internet site found at www.yearstolife.com their colon cleansing services to treat cancer, arthritis, restore the immune system, and for general well-being; ozone steam spa treatments to oxygenate, detoxify and cleanse the lymphatic system; foot bath to remove cholesterol deposits, heavy metals, and uric acid from the body and detoxify the liver, kidney, bladder, etc.; and dietary supplements that claim to treat appendicitis, arthritis, bubonic plague, cancer, diabetes and other diseases. Defendants misbranded their prescription colon irrigation systems under state and federal law by advertising them for uses other than the FDA approved uses; misbranded and adulterated the Ozone Spa devices and Bio-Cleanse devices by advertising unapproved medical devices; and misbranded foods by making unsubstantiated

claims and/or misbranded unapproved new drugs by making drug claims that were not approved by FDA.

20. Defendants also advertised using tri-fold promotional brochures entitled “Years to Your Life Health Centers” and on the internet site for “Ozone Colonics” where ozone is added to the water used in the prescription colon irrigation systems. FDA has not approved the use of ozone with the Jimmy John III colon irrigation systems or rectal nozzles.

21. Defendants also advertised using tri-fold promotional brochures entitled “Years to Your Life Health Centers” for their colon cleansing services to treat cancer, arthritis, restore the immune system, and for general well-being; Ozone Spa treatments to oxygenate, detoxify and cleanse the lymphatic system; and the Bio- Cleanse foot bath to remove cholesterol deposits, heavy metals, and uric acid from the body and to detoxify the liver, kidney, bladder.

22. Defendants failed to disclose on the internet site or the brochure, both described above, that colonic irrigation requires an order from a practitioner licensed in Texas to use or order the use of prescription colon irrigation systems.

23. Defendants’ prescription colon irrigation systems have only been approved by the FDA for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations and not for the uses for which Defendants’ advertise the procedures. Defendants falsely advertised and misbranded their prescription colon irrigation systems by advertising the use of these devices for unapproved uses.

Inspections of November 13, 14, 15, 2002:

24. On November 13, 2002, an investigator from the Texas Department of Health (“TDH”) inspected Defendants’ office at 237 W. Page in Dallas, Texas as a result of a complaint that a 72 year old woman died on August 14, 2002, after using a colonic irrigation device, self-

administered after being told how to use the device on herself, at Defendants' Irving location on April 21, 2002.

25. During the inspection, Defendants were told by telephone by Jimmy Girouard, President of Colon Therapeutics, Inc., and Dick Hoenninger, Executive Director of the International Association for Colon Hydrotherapy that Defendants were involved in a study to reclassify colon irrigation systems for general well being and that they qualified for an Investigational Device Exemption and were therefore allowed to possess the prescription colon irrigation systems. Neither Hoenninger nor Girouard could provide documentation that an IDE study involving these devices was approved by FDA. Defendant PITRE was not able to produce any documentation of the study, study participants, or study protocol and was unaware of any of the FDA requirements involved in participating in such a study. .

26. TDH determined that Defendants purchased and received in commerce in Dallas County, Texas, seven Jimmy John III prescription colon irrigation devices and rectal nozzles, labeled with a statement affixed to them that indicated that federal law restricts the nozzles to sale by or on the order of a physician or health care practitioner, from Colon Therapeutics, Inc., and Jimmy Girouard and that all these devices are considered by FDA to be prescription medical devices.

27. TDH determined that Defendants did not have a licensed practitioner to authorize her purchase or possession of the seven colon irrigation systems or the rectal nozzles.

28. TDH also determined that Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE did not have a licensed practitioner ordering the colon cleansing procedures for patients or supervising Defendants' use of the prescription colon irrigation systems to perform colon cleansing for any purpose.

29. TDH also determined that Defendants performed colon cleansing for a variety of reasons, including but not limited to treating cancer and arthritis, restoring the immune system, and for general well-being.

30. On November 14, 2002, TDH inspected all three of Defendant's offices in Irving, Dallas, and Carrollton and conducted a random review of approximately 71 client records kept by Defendants at their three offices and found that none of these files contained any order for a colon irrigation procedure from a physician and that all of these patients had received colon irrigation procedures using prescription colon irrigation systems provided by Defendants or one of their employees or agents. Records for thousands of other patients were not reviewed at this time.

31. TDH issued "Notices of Detention" on November 13, 14, and 15 2002, notifying Defendants that the Texas Department of Health had detained Defendant's seven Jimmy John III colon irrigation systems and 734 Jimmy John III rectal nozzles after determining that these devices were adulterated, misbranded, and/or violated additional provisions of the TFDCA. The inspection and detention of November 15, 2002, were generated by a complaint that Defendants were using the detained devices and had hidden boxes of rectal nozzles from TDH. The November 15, 2002 complaint investigation did result in the finding of an additional 196 rectal nozzles even though Defendant PITRE had stated on November 14, 2002 that she had produced all of the rectal nozzles for detention.

32. In addition, Defendants were notified verbally during the inspection by TDH that she was not allowed to move, sell, or use the detained devices without permission of TDH. The Notice of Detention form cited to Section 431.021(j) of the Texas Health and Safety Code as declaring that the use, removal, or disposal of a detained article from the premises by sale or

otherwise without written permission from the Commissioner of Health, an authorized agent, or the court to be an unlawful and prohibited act.

Inspection of December 12, 2002:

33. On December 12, 2002, an inspection was conducted by TDH of Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE at their Dallas office. TDH determined that Defendants advertised and provided services using Ion Cleanse or Bio-Cleanse devices for foot baths to remove cholesterol deposits, heavy metals, and uric acid from the body and detoxify the liver, kidney, bladder had not received marketing clearance from the FDA for these or any uses.

34. TDH determined that Defendants advertised and provided services using an Ozone Spa device and one flow regulator unit for ozone steam spa treatments to oxygenate, detoxify and cleanse the lymphatic system had not received marketing clearance from the FDA for these or any uses.

35. TDH also determined Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE advertised and sold dietary supplements that claim to treat appendicitis, arthritis, bubonic plague, cancer, diabetes, blood parasites, gonorrhea, poor blood circulation, irregular body temperature, varicose veins, aneurysms, peptic ulcers, and cholesterol deposits. TDH determined that these claims were unapproved drug claims for products that Defendants' distributed, including Silver Plus, Gold Plus, Copper Plus, and Zinc Plus.

36. TDH also determined that Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE advertised and promoted "Ozone Colonics" where ozone is added to water used in Defendants' prescription colon irrigation devices on their internet site and in a tri-fold brochure. In addition, TDH determined that Defendants advertised and promoted prescription colon irrigation system as effective for treating cancer, arthritis, restoring or renewing the

immune system, removal of toxins from the colon and removal of sources of disease in the body on their internet site and in a tri-fold brochure.

37. TDH determined that Defendants failed to provide evidence that the Jimmy John III prescription colon irrigation devices and rectal nozzles were the subjects of an FDA approved investigational device exemption and failed to obtain informed consent for patients although Defendant PITRE claimed that Defendants were participating in the C3SG colon hydrotherapy general use investigational study even though it was not approved by FDA.

38. TDH determined that Defendants failed to develop, maintain, and implement written procedures to comply with medical device reporting (“MDR”) requirements and failed to submit an MDR report to the device manufacturer and/or to FDA concerning the adverse event, a serious injury and/or death, involving a 72 year old woman within 10 working days of becoming aware of the information.

39. TDH issued a “Notice of Detention” on December 12, 2002, notifying Defendants that the Texas Department of Health had detained Defendant’s two Ion Cleanse or Bio-Cleanse devices, one Ozone Spa device with flow regulator unit, and one bottle each of Colloidal Gold Plus and Copper Plus after determining that these devices and products were adulterated, misbranded, and/or violated additional provisions of the TFDCA.

Inspections of December 23 and January 3, 2003:

40. On December 23, 2002, TDH tried to inspect Defendants at their Dallas office after receiving a complaint that Defendants were using the ozone spa device that had previously been detained. TDH was unable to conduct an inspection because the door was locked and no one answered the door.

41. On January 3, 2003, TDH inspected Defendants ETERNAL HEALTH, INC., and

CYNTHIA PITRE at their Dallas office after receiving a complaint that Defendants were using the ozone spa device that had previously been detained. TDH observed that the ozone spa device had been moved and Defendant PITRE confirmed that it had been turned around for a training session and by the janitor during cleaning but denied that it had been used in violation of the detention.

Inspections of August 7, 12, 13, and 15, 2003:

42. On August 7, 2003, TDH attempted to conducted an investigation at their Dallas, Irving, and Carrollton offices of a complaint that Defendants had been conducting prescription colon irrigation procedures. The investigator determined on August 12 and 15, 2003, that the detained devices had been removed from the Irving and Carrollton locations by Defendant PITRE in violation of state law and that these offices were closed.

43. On August 12 and 13, 2003, TDH confirmed that Defendants had continued to conduct colon cleansing procedures using prescription colon irrigation systems without orders for the procedure and supervision from a licensed practitioner despite notification that this was unlawful as early as November 13, 2002.

44. Defendants performed approximately 1,059 colon irrigation procedures from April 2, 2003 to July 28, 2003 using detained prescription colon irrigation systems and rectal nozzles without orders or supervision from a licensed practitioner.

45. Defendants moved all of the detained devices to a storage facility at 3427 Marvin D. Love Fwy., Storage # 1166, Dallas, Texas 75224 without authorization from TDH prior to moving the detained devices. TDH again placed detention tags on Defendants' seven Jimmy John III colon irrigation systems, two Ion Cleanse or Bio-Cleanse devices, one Ozone Spa device with flow regulator unit, and one bottle each of Colloidal Gold Plus and Copper Plus after

determining that these devices and products were adulterated, misbranded, and/or violated additional provisions of the TFDCA.

46. Defendants did not have any of the approximately 743 detained rectal nozzles during this inspection of the storage facility. The failure to produce the detained rectal nozzles is a violation of state law.

OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES

47. The Texas Food, Drug, and Cosmetic Act lists acts and the causing of acts that are unlawful and prohibited, including, but not limited to, misbranding medical devices in commerce, adulterating medical devices in commerce, and the dissemination of any false advertisement. TDH determines if the use of a medical device violates any prohibited acts depending on the classification and regulation of each medical device by the Federal Food and Drug Administration (“FDA”).

FDA Regulates and Classifies Medical Devices According to Intended Use

48. FDA regulates and classifies medical devices for use in humans according to their intended use, relying upon the manufacturer or distributor’s labeling of the device to determine its intended use. FDA is responsible for classifying and approving medical devices after they determine whether they are safe and effective for their stated intended uses.

49. FDA has classified colon irrigation systems intended for “colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations” as Class II medical devices when used for this purpose in 21 C.F.R. §876.5220 (b)(1). Colon irrigation devices are described as usually consisting of a container for fluid; the tubing; the nozzle; a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled; a console-type toilet and necessary fittings to allow the device to be connected to water and sewer

pipes; and electrical power to heat the water.

50. FDA approved the colon irrigation devices used by Defendants, the Jimmy John III prescription colon irrigation system and the Jimmy John Rectal Nozzle, as “substantially equivalent” to other pre-existing colon irrigation devices used for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations based on premarket notification submissions to the FDA pursuant to § 510(k) of the FDCA, 21 U.S.C. § 360(k). Therefore, these devices are Class II medical devices by regulation for this purpose and can only be used for the approved intended use for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

51. FDA has also classified colon irrigation systems for other uses than the intended use authorized in 21 C.F.R. §876.5220 (b)(1). FDA classified these colon irrigation systems as class III medical devices when the intended use is for “other uses, including colon cleansing routinely for general well being” as shown in 21 C.F.R. §876.5220 (b)(2).

52. FDA’s classification of colon irrigation systems as Class III medical devices requires that any colonic irrigation system to be used for purposes other than those approved in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being shall have an approved premarket approval (“PMA”) in effect before being placed in commercial distribution to show that the device is safe and effective for the new intended use . (21 C.F.R. §876.5220 (c)).

53. FDA requires that, unless specifically exempted, a medical device must have “adequate directions for use” as defined in 21 C.F.R. § 801.5 to mean directions under which the layperson can use a device safely and for the purposes for which it is intended. Unless subject to an exemption, a medical device must have “adequate directions for use” or it cannot be sold to or used by a lay person.

FDA Considers All Colon Irrigation Devices To Be Prescription Medical Devices

54. FDA defines a prescription device in 21 C.F.R. § 801.109 to be a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared.

55. The FDA regulations create an exemption from the requirement of having “adequate directions for use” for prescription medical devices in 21 C.F.R. § 801.109. To qualify for an exemption from “adequate directions for use”, a medical device must be in the possession of a practitioner licensed by state law to use or order the use of such device; sold only to or on the prescription or other order of such practitioner for use in professional practice; and the label has to bear the statement “Caution: Federal law restricts this device to sale by or on the order of a _____, to be filled in with the descriptive designation of any practitioner licensed by state law in which he practices to use or order the use of the device.

56. The FDA considers the colon irrigation devices possessed and used by Defendants to be prescription medical devices, as defined in 21 C.F.R. § 801.109, and these devices must comply with all the requirements as cited in paragraph 53 above in order to be exempted from “adequate directions for use”. Because the colon irrigation devices used by Defendants are prescription devices, these devices cannot bear adequate directions for safe use by a layperson, and therefore must comply with the exemption requirements in paragraph 53.

57. State law incorporates a definition of prescription devices in 25 T.A.C. §229.433 (23) as a “restricted device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a

practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared”.

58. In addition, prescription colon irrigation systems are restricted devices because they are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Restricted devices pursuant to 25 T.A.C. §229.433 (27) are devices that are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Because Defendant LINDA GONZALEZ’s colon irrigation devices are prescription medical devices, under Texas law her devices are also restricted devices since they are subject to certain controls related to the sale, distribution, or use, as defined in 25 T.A.C. §229.433 (27).

59. Prescription colon irrigation devices are “dangerous drugs” pursuant to §483.001 (2) of the Texas Dangerous Drug Act because these devices bear or are required to bear a legend to comply with federal law regarding their sale as prescription medical devices pursuant to 21 C.F.R. § 801.109.

60. Under Texas law, only those practitioners listed in § 483.001(12) of the Texas Dangerous Drugs Act, also defined in 25 T.A.C. §229.433 (22), are authorized to purchase, possess, use or order the use of prescription or restricted medical devices, including prescription colon irrigation devices. The only practitioners licensed in Texas who can purchase, possess, use or order the use of colon irrigation devices on humans in the course of their professional practice are those practitioners licensed by the Texas Board of Medical Examiners.

61. Defendant CYNTHIA PITRE is not a practitioner as defined by 25 T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act and therefore colon irrigation devices in her possession and use are not exempted from having adequate directions for use.

DEFENDANT'S DEVICES ARE MISBRANDED

62. As set out in paragraphs 1 through 61 and incorporated herein, Section 431.112(f)(1) of the TFDCa provides that a device is misbranded unless its labeling bears adequate directions for use or unless the device has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services. Since the prescription colon irrigation systems used by Defendants cannot bear instructions for safe use by a layperson and only are exempt from this requirement pursuant to 21 C.F.R. § 801.109, Defendants are required to have a licensed practitioner to purchase and possess, to order the procedure, and to supervise the use of prescription colon irrigation systems.

63. Defendant CYNTHIA PITRE is not a licensed practitioner as defined by §483.001(12) of The Dangerous Drug Act nor did she have a licensed practitioner authorizing her or Defendant ETERNAL HEALTH, INC.'s purchase and possession, ordering colon cleansing procedures for patients, or supervising the colon cleansing procedures using prescription colon irrigation systems.

64. Defendants' purchase and possession of prescription colon irrigation devices; lack of written orders for colon cleansing procedures for each patient; and the use of colon irrigation systems without authorization and supervision of a practitioner/physician licensed in Texas misbrand these device pursuant to § 431.112 (f) of the TFDCa.

65. Subsequently, Defendants performed colon cleansing without authorization from a practitioner licensed in Texas to purchase, possess, or use prescription colon irrigation systems which are also restricted devices, as defined in by 25 T.A.C. §229.433 (27), since they are subject to certain controls related to the sale, distribution, or use. Therefore, Defendants' purchase, possession, and use of prescription colon irrigation systems as restricted devices without

authorization, a written order for colon cleansing procedures, and supervision by a practitioner licensed in Texas also misbrand these devices pursuant to § 431.112 (r) of the TFDCA.

66. Under the terms of § 431.021(b) of the TFDCA, the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendants' purchase, possession, and use of prescription and restricted medical devices without authorization and supervision by a practitioner licensed in Texas misbrand these devices in Texas.

67. Each colon cleansing that Defendants have performed in Texas without an order from a licensed practitioner or without supervision by practitioner licensed in Texas using prescription colon irrigation systems violates Texas law and is prohibited and unlawful because this use without such an order or supervision from a licensed practitioner misbrands the colon irrigation devices.

DEFENDANT'S DEVICES ARE ADULTERATED

68. As set out in paragraphs 1 through 67 and incorporated herein, prescription colon irrigation systems used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including to treat cancer, arthritis, restore the immune system, and for general well being purposes, have not been approved previously by FDA and are, therefore, not preamendment devices and are by regulation (21 C.F.R. §876.5220 (b)(2)) and by statute classified as Class III medical devices and may not be marketed without an approved application for Premarket Approval ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act. FDA has not approved any application for PMA for prescription colon irrigation devices for any purposes, including to treat cancer, arthritis, restore the immune system, and general well being.

69. The prescription colon irrigation systems used by Defendants are Class III medical devices when used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including

colon cleansing routinely for general well being and to treat cancer, arthritis, and restore the immune system, require premarket approval, or must fall into an exemption from such approval, before they can be used in the marketplace. FDA must review each Class III medical device to determine if it is safe and effective for its use(s) before the device can be introduced into commerce.

70. Defendants' colon irrigation devices are Class III medical devices when used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including to treat cancer, arthritis, and restore the immune system and general well being, and were required to receive premarket approval from FDA, but are used in commerce even though they did not receive such approval. (21 U.S.C.A. §351(f) (1)(A), section 501(f)(1)(A) of the FFDCA). A device is adulterated if it is a Class III medical device, whether by statute or regulation, and is in the marketplace without receiving approval from FDA.

71. Defendants' prescription colon irrigation systems are adulterated under state law, according to §431.111(f)(1)(A) of the TFDCA. Section 431.111 states that a device shall be deemed to be adulterated :

(f)(1) if it is a class III device:

(A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or
(II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

72. Under the terms of § 431.021(b) of the TFDCA, the adulteration of any device in commerce in Texas is unlawful and prohibited. Defendants violate § 431.021(b) of the TFDCA

and adulterate their prescription colon irrigation systems with each use that FDA codifies as a Class III medical device use, including to treat cancer, arthritis, restore the immune system, and general well being, since these devices have not been approved through pre-market approval as required by FDA to show their safety and effectiveness for Class III uses.

73. Defendants' Ozone Spa treatments to oxygenate, detoxify and cleanse the lymphatic system and the Bio- Cleanse foot bath to remove cholesterol deposits, heavy metals, and uric acid from the body and to detoxify the liver, kidney, bladder have not been approved previously by FDA and are, therefore, not preamendment devices by statute classified as Class III medical devices and may not be marketed without an approved application for Premarket Approval ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act. FDA has not approved any application for PMA for Ozone Spa devices or for Ion Cleanse or Bio-Cleanse devices for any purposes. Defendants' Ozone Spa and Ion Cleanse or Bio-Cleanse devices are adulterated under the terms of § 431.021(b) of the TFDCA.

DEFENDANT'S ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE

74. As set out in paragraphs 1 through 73 and incorporated herein by reference, Defendants represented that her prescription colon irrigation systems have uses other than those for which FDA has allowed the devices to be sold or used, including to treat cancer, arthritis, restore the immune system, and for general well being. Defendants' representations for the use of prescription colon irrigation devices for unapproved uses constitute false advertisements in violation of § 431.021(f) of the TFDCA.

75. Defendants also have violated § 431.021(f) of the TFDCA because Defendants' representations of the illegal use of all their prescription colon irrigation systems, including rectal nozzles, their Ozone Spa device, and their Ion Cleanse or Bio-Cleanse medical devices in their internet site or in their brochure constituted false advertisements under the TFDCA because they

solicited persons to purchase services which are unlawful and violate § 431.021(b) of the TFDCA.

76. Defendants advertised and promoted the unapproved use of prescription colon irrigation systems to the public through their internet site and brochures although these devices are not intended for self-medication or for use without practitioner supervision and ordering without disclosing that these acts are unlawful and prohibited by the TFDCA.

77. Such representations listed above constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' services for unapproved uses of prescription colon irrigation devices without involvement of a practitioner licensed in Texas.

78. Any such advertisement by Defendants of a prescription medical device directed toward the public without disclosing that a licensed practitioner must order the colon cleansing procedure to be administered with prescription colon irrigation systems and for unapproved uses are declared to be false by the terms of §431.182(a) of the TFDCA.

PROHIBITED ACTS

79. Defendants, as set out in paragraphs 1 through 78 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA with each colon cleansing performed using prescription medical devices without an order or supervision by a licensed practitioner:

- a. Introducing and delivery into commerce a misbranded or adulterated prescription colon irrigation system with each use of Defendants' prescription colon irrigation devices, in violation of §431.021(a);
- b. Misbranding of a prescription colon irrigation system in commerce, in violation of §431.021(b);
- c. Adulteration of a prescription colon irrigation system in commerce, in violation of §431.021(b)
- d. Receiving in commerce a prescription colon irrigation system that is adulterated or misbranded, in violation of §431.021(c);

- e. Disseminating false advertising, in violation of §431.021(f);
- f. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a prescription colon irrigation system for a new or unapproved use, unless exempt by a 520(g) investigational device exemption, in violation of § 431.021(t)(1)(A);
- g. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved, in violation of § 431.021(t) (1)(B);
- h. Failing to comply with federal medical device reporting requirement to report a serious injury and/or death, as required by 21 CFR § 803 and Section 519 of the federal Act, in violation of § 431.021(t) (1)(B); and
- i. Removing or using a detained article, in violation of §431.021(j).

VIOLATIONS OF THE DTPA

80. Defendants, as set out in paragraphs 1 through 79 and incorporated herein by reference, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

- a. Causing confusion as to the approval of a good by using prescription colon irrigation systems without the authorization or supervision of a practitioner licensed in Texas;
- b. Failing to disclose that prescription colon irrigation systems are only to be sold under the order of a practitioner licensed in Texas and Defendants' possession of the devices violate state law;
- c. Failing to disclose that prescription colon irrigation systems are only to be used under the supervision of a practitioner licensed in Texas and Defendants do not have the required supervision;
- d. Failing to disclose that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner in Texas;
- e. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a practitioner licensed in Texas;

- f. Failing to disclose that federal and state law prohibit colon cleansing using prescription colon irrigation systems to treat cancer, arthritis, restore the immune system, and for general well-being because these uses have not been proven to be safe and effective to FDA;
- g. Falsely advertising that colon cleansing using prescription colon irrigation systems is appropriate for self-administration when it is not;
- h. Failing to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only;
- i. Failing to disclose that Defendant's Ozone Spa device and Bio-Cleanse devices have not been cleared by FDA for marketing for any purpose; and
- j. Falsely representing that the use of Defendants' Ozone Spa device and Ion Cleanse or Bio-Cleanse medical devices are lawful.

81. Moreover, the Consumer Protection Division has reason to believe that the above actions specifically violate §17.46 (a) and the following provisions of §17.46 of the DTPA:

- (b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;
- (b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
- (b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

INJURY TO CONSUMERS

82. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

CONTINUING VIOLATIONS

83. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 82 above, Defendants have violated and will continue to violate the laws as hereinabove alleged. Defendants, unless restrained by this Honorable Court, will continue violating the laws of the State of Texas and injury, loss and damage will result to the State of Texas and to the general public. Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE have violated and continue to violate these sections of the TFDCA and the DTPA.

PRAYER

84. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- a. Introducing and delivering into commerce misbranded or adulterated prescription colon irrigation systems, including rectal nozzles;
- b. Misbranding or adulteration of prescription colon irrigation systems, including rectal nozzles in commerce;
- c. Receiving in commerce prescription colon irrigation systems, including rectal nozzles that are adulterated or misbranded;
- d. Disseminating false advertising about prescription colon irrigation systems, including rectal nozzles;

- e. Removing or using detained prescription colon irrigation systems, including rectal nozzles;
- f. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation device for a new or unapproved use, unless exempt by a 520(g) investigational device exemption;
- g. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved;
- h. Failing to comply with federal medical device reporting requirements, as required by 21 CFR § 803;
- i. Purchasing and possessing prescription colon irrigation systems, including rectal nozzles, without a practitioner licensed under Texas law to purchase and possess such devices;
- j. Using prescription colon irrigation systems, including rectal nozzles, without the supervision of a practitioner licensed by Texas law to use such devices;
- k. Using prescription colon irrigation systems, including rectal nozzles, without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;
- l. Using prescription colon irrigation systems, including rectal nozzles for treating diseases of the body or for uses, including general well being for which FDA has not approved these devices;
- m. Failing to disclose that federal and state law prohibit colon cleansing using prescription colon irrigation systems to treat cancer, arthritis, restore the immune system, and for general well-being because these uses have not been proven to be safe and effective to FDA;
- n. Falsely advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles, can be self-administered;
- o. Falsely advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles, are effective for treating diseases of the body and for general well being for which FDA has not approved these devices;
- p. Failing to provide a notice required by Section 510 (k) of the Federal Act or file an application for premarket approval as required by Section 515 of the Federal Act prior to introducing into commerce a prescription colon irrigation device, including a rectal nozzle, for a new or unapproved use;

- q. Causing confusion as to the approval of a good by advertising to consumers the use prescription colon irrigation systems, including rectal nozzles, for self-use;
- r. Failing to disclose that the prescription colon irrigation systems are only to be used under the written order and supervision of a practitioner licensed in Texas;
- s. Using prescription colon irrigation systems, including rectal nozzles, that have been detained by the Texas Department of Health unless the detention has been released; and
- t. Failing to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

85. Plaintiff further prays that upon final hearing that this Court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE, within 30 days of the order signed by the Court, at her own expense to destroy all devices pursuant to § 431.050 of the TFDCA, currently detained by TDH, unless said devices are brought into compliance with Chapter 431 and have been released from detention by TDH based upon Defendant's assurance that the devices will be used in a manner consistent with the law and the terms of this injunction or transferred or sold to a licensed practitioner for the practitioner's use in his/her own practice.

86. Plaintiff further prays that upon final hearing this Court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE to pay civil penalties to the State of Texas up to \$25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

87. Plaintiff further prays that upon final hearing that this court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE to pay to the State of Texas and to the TEXAS COMMISSIONER OF HEALTH their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees pursuant to § 431.047(d) of the TFDCA.

88. Plaintiff further prays that upon final hearing this Court order Defendants

ETERNAL HEALTH, INC., and CYNTHIA PITRE to restore all money or other property taken from identifiable persons by means Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE's unlawful acts or practices, or, in the alternative, award judgment for damages to compensate identifiable persons for such losses as provided in §17.47(d) of the DTPA.

89. Plaintiff further prays, that upon final hearing, this Court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

90. Plaintiff further prays that upon final hearing this Court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE to pay an additional amount in civil penalties, not to exceed a total of \$250,000.00, to the State of Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

91. Plaintiff further prays that upon final hearing that this Court order Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE to pay to the STATE OF TEXAS attorney fees and to pay the costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

92. Plaintiff further prays that the court set this matter for trial and upon final hearing issue a permanent injunction against Defendants ETERNAL HEALTH, INC., and CYNTHIA PITRE .

93. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

Plaintiff State of Texas

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